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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/708,564

03/11/2004

Darin R. Okerlund

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EXAMINER

WEATHERBY, ELLSWORTH

ART UNIT

PAPER NUMBER

3768

MAIL DATE

DELIVERY MODE

09/02/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/708,564	<b>Applicant(s)</b> OKERLUND ET AL.	
	<b>Examiner</b> ELLSWORTH WEATHERBY	<b>Art Unit</b> 3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 and 6-31 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 and 6-31 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/18/2007 has been entered.

### ***Terminal Disclaimer***

2. The terminal disclaimer filed on 12/18/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of USPN 7,286,866 has been reviewed and is accepted. The terminal disclaimer has been recorded.

### ***Claim Objections***

3. Claims 1-4, 6-31 are objected to because of the following informalities:  
Regarding claims 1, 9, 16 and 22, these claims fail to positively set forth a step/means for saving views of the 3D model. Accordingly, reference to *registering saved views* lacks antecedent basis. Regarding claims 2 and 3, "the ventricles" lacks antecedent basis. Regarding claims 10, 17, and 23, "the ventricles" lacks antecedent basis in view of the parent claims from which they claim only referring to *the left ventricle*. Regarding claim 15, it is not clear what further step in the method is set forth. Regarding claim 18,

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there is no antecedent basis for the limitation ""immersive view"". Accordingly, the examiner is interpreting "immersive views" to read *interior views* in accordance with the claimed "interior views" of parent claim 17. Regarding claim 27, the claim includes functional language unsupported by structure to produce such a function. Regarding claim 31, it is not clear what further structural limitation has been set forth. Appropriate correction is required.

### ***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1, 3, 9, 12, 15, 16, 19, 22, 23 and 27 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 9, 12, 16, 17, 25, 27, 35 of U.S. Patent No. 7,343,196. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application and the conflicting '196 patent teach planning an invasive procedure by

obtaining acquisition data from a medical imaging system, generating a 3D model of target, identifying one or more anatomical landmarks on the model and inserting geometric markers thereat, registering the saved views on an interventional system and visualizing the view on the system. Both also teach segmenting the acquisition data.

6. The present application and the conflicting patent differ in that the present application is applied to MIDCAB where the conflicting '196 patent teaches planning biventricular pacing lead placement. However, the Examiner stands that both procedures utilize the same system. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the method of the present application to plan a biventricular pacing lead placement. The motivation to modify the present application would have been to provide increased utility of the present application without additional hardware or steps.

7. Claims 9, 10, 11, 15, 16, 17 and 18 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 9, 10 of U.S. Patent No. 7,346,381. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present application and the conflicting '381 patent teach planning an invasive procedure by obtaining acquisition data from a medical imaging system, generating a 3D model of the target, identifying one or more anatomical landmarks on the model and inserting geometric markers thereat, registering the saved views on an interventional system and visualizing the views of the 3D model having the geometric markers on the system. Both also teach segmenting the acquisition data. Both also teach generating interior views

8. The present application and the conflicting patent differ in that the present application is specifically applied to MIDCAB where the conflicting '381 patent is applied to procedures having a coronary sinus. The '381 also includes a limitation on the number of geometric markers. However, the Examiner stands that both procedures utilize the same system. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the method of the present application to plan a coronary sinus procedure. The motivation to modify the present application would have been to provide increased utility of the present application without additional hardware or steps.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 1, 3-4, 6, 8, 22-28, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (Pub. No.: 2004/0210125) in view of Coste-Maniere et al. (Pub. No.: 2003/0109780).

11. Chen et al. (hereinafter Chen) teaches a method for advanced surgical planning comprising: obtaining acquisition data from a medical imaging system [0008]; generating a 3D model of the structure [0008]; identifying one or more anatomical landmarks *on the 3D model* and inserting corresponding geometric markers thereat,

utilizing user input at an operator console [0011-0013; 0027; 0030]; registering saved views of the 3D model on a workstation of an interventional system, the saved views having the geometric markers [0013; 0016; 0027; 0052]; and visualizing one or more of the registered saved view on a display screen of the interventional system [0013; 0027; 0054]. Chen also teaches registering the surgical instrument on the interventional system and generating interior views [0023-0024].

12. Chen does not expressly teach that the method is for planning minimally invasive direct coronary bypass for a patient. Chen also does not expressly teach that the acquisition data is EKG gated or implemented with protocols directed for imaging the coronary arteries and ventricles. Chen also does not expressly teach quantifying distance and location information for a cardiac point of interest, and identifying an incision location and path for MIDCAB based on the quantified distance and location information for the cardiac point of interest to reduce a size of an incision.

13. Coste-Maniere et al. hereinafter (Coste-Maniere) teaches generating models for minimally invasive surgical planning [abstract; 0003], the method applicable to minimally invasive coronary artery bypass surgery [0050]. Coste-Maniere also teaches that the acquisition data is implemented with protocols directed for imaging the coronary arteries and ventricles and may be EKG gated [0050]. Coste-Maniere also teaches registering MIDCAB instrument on the interventional system [0070]. Coste-Maniere also teaches quantifying distance and location information for a cardiac point of interest, and identifying an incision location and path for MIDCAB based on the quantified distance and location information for the cardiac point of interest to reduce [0005; 00010; 0036; 0055-0057; 0098; 0103].

14. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Chen in view of Coste-Maniere. The motivation to modify Chen in view of Coste-Maniere would have been to apply modern surgical planning techniques to minimally invasive coronary artery bypass operations, a technique which is known in the art, as shown by Coste-Maniere [0005; 0050].

15. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (Pub. No.: 2004/0210125) in view of Coste-Maniere et al. (Pub. No.: 2003/0109780) as applied to claims 1 above, and further in view of Keston et al. (USPN 6,493,575).

16. Chen in view of Coste-Maniere teaches all the limitations of the claimed invention except for expressly teaching that the method further comprises identifying from the 3D model, orientation, size and dimensions of the coronaries and ventricles.

17. In a similar field of endeavor, Keston et al. (hereinafter Keston) teaches identifying from a 3D model, orientation, size and dimensions of the ventricles and arteries (abstract; col. 16, l. 65- col. 17, l. 5; col. 17, ll. 40-47; col. 18, ll. 5-41).

18. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Chen in view of Coste-Maniere with Keston. The motivation to modify Chen in view of Coste-Maniere with Keston would have been would have been to accurately determine the location of the surgical procedure on a cardiac model.

19. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (Pub. No.: 2004/0210125) in view of Coste-Maniere et al. (Pub. No.: 2003/0109780)



as applied to claim 1 above, and further in view of Veseley et al. (U.S. Patent No. 6,246,898).

Chen in view of Coste-Maniere teaches all the limitations of the claimed invention except for expressly teaching that the method further includes measuring the size, extent and number of lesions in the coronary artery.

In the same field of endeavor, Veseley et al. (hereinafter Veseley) teaches determining the 3D topographical properties of lesions to in the coronary arteries (col. 22, lines 12-27). Here, the examiner has interpreted the limitations includes measuring the size, extent and number of lesions in the coronary artery to be met because identifying the topographical properties of lesions inherently includes identifying size, extent and number of lesions in the coronary artery, thereby allowing the physician to confidently make a diagnosis.

It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the method of Chen in view of Coste-Maniere with Veseley. The motivation to modify Chen in view of Coste-Maniere with Veseley would have been to improve the diagnostic utility and improve characterization of the diseased arteries.

20. Claims 9-13, 15-20, 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (Pub. No.: 2004/0210125) in view of Coste-Maniere et al. (Pub. No.: 2003/0109780) and Krishnan et al. (Pub. No.: 2005/0059876).

21. Chen et al. (hereinafter Chen) teaches a method for advanced surgical planning comprising: obtaining acquisition data from a medical imaging system [0008]; generating a 3D model of the structure [0008]; identifying one or more anatomical

landmarks *on the 3D model* and inserting corresponding geometric markers thereat, utilizing user input at an operator console [0011-0013; 0027; 0030]; registering saved views of the 3D model on a workstation of an interventional system, the saved views having the geometric markers [0013; 0016; 0027; 0052]; and visualizing one or more of the registered saved view on a display screen of the interventional system [0013; 0027; 0054]. Chen also teaches registering surgical instruments and displaying associated internal views through the display screen associated with the interventional system [0023-0024].

22. Chen does not expressly teach that the method and acquisition data is directed toward planning a minimally invasive direct coronary bypass. Chen also does not expressly teach segmenting the acquisition data using a 3D protocol so as to visualize the coronary arteries and left ventricle. Chen also does not expressly teach identifying from the 3D model, orientation and any anomalies associated with the coronary arteries and the left ventricle. Chen also does not expressly teach that the acquisition data is EKG gated. Chen also does not expressly teach quantifying distance and location information for a cardiac point of interest, and identifying an incision location and path for MIDCAB based on the quantified distance and location information for the cardiac point of interest.

23. Coste-Maniere et al. hereinafter (Coste-Maniere) teaches generating models for minimally invasive surgical planning [abstract; 0003], the method applicable to minimally invasive coronary artery bypass surgery [0050]. Coste-Maniere also teaches that the acquisition data is implemented with protocols directed for imaging the coronary arteries and ventricles and may be EKG gated [0050]. Coste-Maniere also teaches segmenting

the acquisition data using a 3D protocol so as to visualize the coronary arteries and left ventricle [0048; 0051-0053; 0081]. Coste-Maniere also teaches registering MIDCAB instrument on the interventional system [0070]. Coste-Maniere also teaches quantifying distance and location information for a cardiac point of interest, and identifying an incision location and path for MIDCAB based on the quantified distance and location information for the cardiac point of interest to reduce [0005; 00010; 0036; 0055-0057; 0098; 0103].

24. Coste-Maniere does not expressly teach identifying, from the 3D model, orientation and any anomalies associated with the coronary arteries and the left ventricle.

25. In a similar field of endeavor, Krishnan et al. (hereinafter Krishnan) teaches identifying from a 3D model, orientation, size and dimensions of the ventricles and arteries [0033; 0077-0078; 0081; 0084]. Krishnan also teaches assessing regional myocardial function using obtained features (abstract).

26. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Chen in view of Coste-Maniere. The motivation to modify Chen in view of Coste-Maniere would have been to prepare a MIDCAB technique using modern surgical planning techniques based on current diagnostic data.

27. Claims 14 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (Pub. No.: 2004/0210125) in view of Coste-Maniere et al. (Pub. No.: 2003/0109780) and Krishnan et al. (Pub. No.: 2005/0059876) as applied to claims 9 and 20 above, and further in view of Veseley et al. (U.S. Patent No. 6,246,898).

Chen in view of Coste-Maniere and Krishnan teaches all the limitations of the claimed invention except for expressly teaching that the method further includes measuring the size, extent and number of lesions in the coronary artery.

In the same field of endeavor, Veseley et al. (hereinafter Veseley) teaches determining the 3D topographical properties of lesions to in the coronary arteries (col. 22, lines 12-27). Here, the examiner has interpreted the limitations includes measuring the size, extent and number of lesions in the coronary artery to be met because identifying the topographical properties of lesions inherently includes identifying size, extent and number of lesions in the coronary artery, thereby allowing the physician to confidently make a diagnosis.

28. It would have been obvious to one of ordinary skill in the art at the time of the invention to have modified the method of Chen in view of Coste-Maniere and Krishnan with Veseley. The motivation to modify Chen in view of Coste-Maniere and Krishnan with Veseley would have been to improve the diagnostic utility and improve characterization of the diseased arteries.

### ***Response to Arguments***

29. Applicant's arguments with respect to claims 1-4 and 6-31 have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLSWORTH WEATHERBY whose telephone number

is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ruth S. Smith/  
Primary Examiner, Art Unit 3737

EW